

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

United States Patent and Trademark
Office
(Box PCT)
Crystal Plaza 2
Washington, DC 20231
ÉTATS-UNIS D'AMÉRIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 21 May 1999 (21.05.99)
--

International application No. PCT/GB98/03068

International filing date (day/month/year) 12 October 1998 (12.10.98)
--

Applicant's or agent's file reference
P/3636.WO MP

Priority date (day/month/year)
15 October 1997 (15.10.97)

Applicant WATTS, Robert, John

1. The designated Office is hereby notified of its election made:

in the demand filed with the International Preliminary Examining Authority on:

14 April 1999 (14.04.99)

in a notice effecting later election filed with the International Bureau on:

2. The election was

was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Lazar Joseph Panakal Telephone No.: (41-22) 338.83.38
---	--

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference P/3636.WO MP	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/GB 98/ 03068	International filing date (day/month/year) 12/10/1998	(Earliest) Priority Date (day/month/year) 15/10/1997
Applicant WATTS, Robert, John		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 5 sheets.

It is also accompanied by a copy of each prior art document cited in this report.

1. Certain claims were found unsearchable (see Box I).
2. Unity of invention is lacking (see Box II).
3. The international application contains disclosure of a **nucleotide and/or amino acid sequence listing** and the international search was carried out on the basis of the sequence listing
 - filed with the international application.
 - furnished by the applicant separately from the international application,
 - but not accompanied by a statement to the effect that it did not include matter going beyond the disclosure in the international application as filed.
 - Transcribed by this Authority
4. With regard to the title, the text is approved as submitted by the applicant.
 the text has been established by this Authority to read as follows:
5. With regard to the abstract,
 - the text is approved as submitted by the applicant.
 - the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this International Search Report, submit comments to this Authority.
6. The figure of the drawings to be published with the abstract is:

Figure No. 3 as suggested by the applicant. None of the figures.

because the applicant failed to suggest a figure.

because this figure better characterizes the invention.

INTERNATIONAL SEARCH REPORT

International application No.

GB 98/03068

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:

2. Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Claims 1-16 are related to an ankle-foot orthosis for resisting plantarflexion, comprising a resiliently flexible sock-like structure enveloping and claims 29-32 are related to a kit comprising the orthosis.

Claims 17-28 are related to an ankle-foot orthosis for resisting plantarflexion, comprising a resilient rib locatable along a portion of the dorsal aspect of the patient's foot and claims 29-32 are related to a kit comprising the orthosis.

The technical relationship between the two inventions defined in the claims lack a common special technical feature, which defines a contribution over the prior art.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/GB 98/03068

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61F 5/01

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPI

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 455934 A (A.PHILIPP), 24 December 1985 (24.12.85), column 4, line 41, figures 1,2, abstract --	1-16,29-32
X	US 5257969 A (C.MANCE), 2 November 1993 (02.11.93), column 3, line 19 - line 29; column 6, line 11 - line 14, figure 6 --	1-3
X	US 5676641 A (S.ARENSDORF ET AL), 14 October 1997 (14.10.97), figures 3,5, abstract --	1-3
X	US 3504668 A (R.E.BOUDON), 13 Sept 1967 (13.09.67), column 2, line 15 - line 19, figures 2-4 --	17-32

 Further documents are listed in the continuation of Box C. See patent family annex.

- * Special categories of cited documents:
- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed
- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- "&" document member of the same patent family

Date of the actual completion of the international search

10 February 1999

Date of mailing of the international search report

25.02.1999

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk
Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl.
Fax: (+ 31-70) 340-3016

Authorized officer

INGRID FALK

INTERNATIONAL SEARCH REPORT

International application No.

PCT/GB 98/03068

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4651723 A (K. SATOH), 24 March 1987 (24.03.87), figures 2-5 --	17
A	GB 2188550 A (JOHN ALAN DREW), 7 October 1987 (07.10.87), claim 9 -----	29-32

INTERNATIONAL SEARCH REPORT

Information on patent family members

21/12/98

International application No.

PCT/GB 98/03068

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 455934 A	24/12/85	NONE	
US 5257969 A	02/11/93	NONE	
US 5676641 A	14/10/97	NONE	
US 3504668 A	13/09/67	NONE	
US 4651723 A	24/03/87	DE 3610532 A	01/10/87
GB 2188550 A	07/10/87	NONE	

PATENT COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P/3636.WO	FOR FURTHER ACTION		See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/GB98/03068	International filing date (day/month/year) 12/10/1998	Priority date (day/month/year) 15/10/1997	
International Patent Classification (IPC) or national classification and IPC A61F5/01			
Applicant WATTS, Robert, John			

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 7 sheets, including this cover sheet.

This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 8 sheets.

3. This report contains indications relating to the following items:

- I Basis of the report
- II Priority
- III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV Lack of unity of invention
- V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability: citations and explanations supporting such statement
- VI Certain documents cited
- VII Certain defects in the international application
- VIII Certain observations on the international application

Date of submission of the demand 14/04/1999	Date of completion of this report 24. 01. 00
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer De Meyere, P Telephone No. +49 89 2399 7466



INTERNATIONAL PRELIMINARY
EXAMINATION REPORT

International application No. PCT/GB98/03068

I. Basis of the report

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

Description, pages:

1.2.6.7 as originally filed

3-5,8,9 as received on 29/11/1999 with letter of 26/11/1999

Claims, No.:

1-22 as received on 29/11/1999 with letter of 26/11/1999

Drawings, sheets:

1/3-3/3 as originally filed

2. The amendments have resulted in the cancellation of:

the description. pages: 3, 4, 5, 8, 9
 the claims. Nos.: 23-32
 the drawings. sheets:

3. This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

see separate sheet

4. Additional observations, if necessary:

INTERNATIONAL PRELIMINARY
EXAMINATION REPORT

International application No. PCT/GB98/03068

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims
	No:	Claims 1-4, 8, 10, 15, 16
Inventive step (IS)	Yes:	Claims
	No:	Claims 5-7, 9, 11-14, 17-22
Industrial applicability (IA)	Yes:	Claims 1-22
	No:	Claims

2. Citations and explanations

see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET

International application No. PCT/GB98/03068

1. Re Item I

Basis of the report

The amendments filed with the letter dated November 6, 1999 introduce subject-matter that extends beyond the content of the application as filed, contrary to Article 34(2)(b) PCT.

The amendment concerned is the following, supplied as claim 1: "in that said orthosis provides, in use, a predetermined substantially constant resistance to planterflexion of the patient's foot". This is not disclosed in the original application.

Claim 1 has been examined based on the originally filed claim.

2. Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

2.1. Reference is made to the following documents:

D1: US 455 934 A (A.PHILIPP) 24 December 1985

D2: US 5 676 641 A (S.ARENSDORF ET AL) 14 October 1997

2.2. The documents D1 and D2 are regarded as the closest prior art to the subject-matter of claim 1, and show (the references in parentheses applying to these documents):

an ankle-foot orthosis for resisting plantarflexion of a patient's foot, the orthosis comprising: a resiliently flexible sock-like structure (1; 20) enveloping, in use, at least a portion of a patient's lower leg in the vicinity of the ankle and at least a portion of the plantar and dorsal aspects of the patient's foot.

Claim 1 does not seem new according to article 33(2) PCT.

2.3. Also the dependent **claims 2 to 4, 8 and 10** do not seem new according to Article 33(2) PCT because:

2.4. D1 and D2 disclose an orthosis, comprising a reinforcing means (7; 34, 50) for

providing a further resistance to planterflexion of the patient's foot.

2.5. D2 discloses an orthosis, wherein the reinforcing means comprises a length of tape (34, 50), the ends of the tape being joined together to form a figure-of-eight passing under the instep, behind the ankle and crossing on the dorsal aspect of the foot.

2.6. D1 discloses an orthosis wherein the reinforcing means comprises a rib (7) running along at least a portion of the dorsal aspect of the foot and substantially midway between the medial malleolus and the lateral malleolus.

2.7. Claim 8 does not seem to be **new** according to article 33(2) PCT because D1 discloses an orthosis wherein the rib is of ortholene (col 4, line 41).

2.8. D1 and D2 disclose an orthosis wherein the reinforcing means (7; 34, 50) has a greater resilience than the sock-like structure.

2.9. The object of claims 5-7 and 9 do not seem inventive because these variations in the material of the rib are merely straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem posed.

2.10. Dependent claims 11 to 14 do not seem to be **inventive** according to article 33(3) PCT because:

2.11. The addition of an insertion slit with alternative closing means is a slight constructional change in the orthosis of D1 which comes within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen.

2.12. Claims 15 and 16 do not seem **new** according to article 33(2) PCT because:

2.13. D1 discloses an orthosis, particularly in Figure 1 and the corresponding description wherein the orthosis envelops at least a portion of the dorsal and plantar aspects of the foot without enveloping the toes.

2.14. D2 discloses an orthosis, particularly in Figure 3 and the corresponding description wherein the orthosis envelops at least a portion of the plantar aspects of the foot without enveloping the calcaneum.

2.15. Claim 17 does **not** seem to be **inventive** according to article 33(3) PCT because in D1 (col 3, line 10) it is specified that the sock consists of an elastic fabric. It would be obvious for the person skilled in the art to use silicone for this application.

2.16. Claim 18 and 22 do **not** appear to be **inventive** according to article 33(3) because a variation of the colour would be made by the person skilled in the art without the use of inventive skills.

2.17. Claims 19 and 20 do not seem inventive because it would be obvious for the person skilled in the art to produce the orthoses according to different production methods in function of the desired characteristics or used materials.

2.18. For **claim 21** it appears that putting several orthoses in a kit does not involve any inventive activity (article 33(3) PCT).

3. Re Item VII

Certain defects in the international application

3.1. Independent **claim 1** is not in the two-part form according to Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in a preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in a characterising part (Rule 6.3(b)(ii) PCT).

3.2. The description is not in conformity with the claims as required by Rule 5.1(a)(iii) PCT.

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB98/03068

4. Re Item VIII

Certain observations on the international application

Claims 1, 3, 4, 15 and 16 do not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The functional statement "aspects" of the patient's foot" does not enable the skilled person to determine which technical features are necessary to perform the stated function.

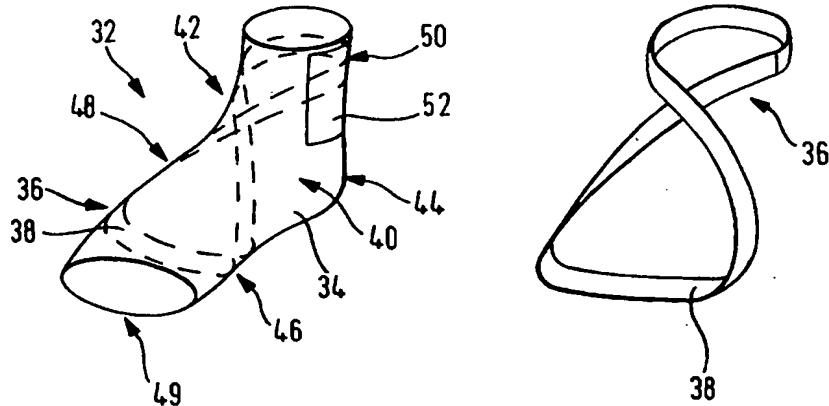
This term could be substituted by "side".



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61F 5/01		A1	(11) International Publication Number: WO 99/18896
			(43) International Publication Date: 22 April 1999 (22.04.99)
(21) International Application Number:	PCT/GB98/03068	(81) Designated States:	AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, ÜG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).
(22) International Filing Date:	12 October 1998 (12.10.98)		
(30) Priority Data: 9721863.0 15 October 1997 (15.10.97) GB 9814726.7 7 July 1998 (07.07.98) GB			
(71)(72) Applicant and Inventor: WATTS, Robert, John [GB/GB]; Venards Cottage, North Gorley, Fordingbridge, Hampshire SP6 2PJ (GB).			
(74) Agents: PURVIS, William, Michael, Cameron et al.; D. Young & Co., 21 New Fetter Lane, London EC4A 1DA (GB).			Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

(54) Title: ANKLE-FOOT ORTHOSIS



(57) Abstract

One embodiment provides an ankle-foot orthosis (32) for resisting plantarflexion of a patient's foot, the orthosis (32) comprising: a resiliently flexible sock-like structure (34) enveloping, in use, at least a portion of a patient's lower leg in the vicinity of the ankle and at least a portion of the plantar (46) and dorsal (48) aspects of the patient's foot. Another embodiment provides an ankle-foot orthosis (1) for resisting plantarflexion of a patient's foot, the orthosis (1) comprising: a resilient rib (3) locatable, in use, along and in abutment with at least a portion of the dorsal aspect of the patient's foot and at least a portion of the patient's lower leg, the orthosis (1) comprising means (7) for securing the rib (3) to the patient's foot and lower leg.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		

and fit as they must be closely fitted to the feet and legs of the patient, and as they are made from relatively expensive materials.

It is an object of aspects of the invention to alleviate some or all of these disadvantages.

5 In accordance with the invention, there is provided an ankle-foot orthosis for resisting plantarflexion of a patient's foot, the orthosis comprising: a resiliently flexible sock-like structure enveloping, in use, at least a portion of a patient's lower leg in the vicinity of the ankle and at least a portion of the plantar and dorsal aspects of the patient's foot.

10 Thus, this aspect of the invention provides a discrete arrangement which adequately resists plantarflexion without requiring the patient to wear a shoe.

15 Preferably the orthosis comprises a reinforcing means for further resisting planterflexion of the foot. The reinforcing means may be a length of tape, the ends of the tape being joined together to form a figure-of-eight passing under the instep, behind the ankle and crossing on the dorsal aspect of the foot. Alternatively, the reinforcing means may comprises a rib running along at least a portion of the dorsal aspect of the foot and substantially midway between the medial malleolus and the lateral malleolus. Preferably the reinforcing means has a greater resilience than the sock-like structure.

20 The sock-like structure may be defined by the rib and a pair of straps, one secured to either end of the rib and respectively securable about the plantar aspect of the foot and the portion of the patient's lower leg in the vicinity of the ankle.

25 Preferably, the orthosis comprises an insertion slit extending midway between the medial malleolus and the lateral malleolus towards the calcaneum, means being provided to securely close the slit once the patient's foot has been inserted in the orthosis.

30 The closing means may comprise a mechanical hook and loop fastener, a set of hoops or hooks being provided adjacent one edge of the slit and a corresponding set of hooks or hoops being provided on a closure member affixed to the other side of the slit, respective hooks and loops being connectable to securely close the slit. Alternatively, the closing means may comprise a zip fastener secured to opposite sides

REPHRASED BY NPL34

of the slit. As a further alternative, the closing means may comprise a set of eyelets closable by a lace.

Preferably, the orthosis envelops the dorsal and plantar aspects of the foot without enveloping the toes. Preferably, the orthosis envelops the plantar aspect of 5 the foot without enveloping the calcaneum. The orthosis could envelop the calcaneum if, for example, mechanical correction of the heel bone is required. The device may also be contoured on the surface abutting, in use, the plantar aspect of the foot to aid support of the metatarsals and to position the foot correctly.

Preferably, the sock-like structure is of silicone. Preferably, the sock-like 10 structure is a 35 shore silicone elastomer, or a higher or lower shore silicone elastomer. Preferably, the reinforcing means is of silicone.

Preferably, the orthosis is skin coloured and/or fabricated by injection moulding. The orthosis could alternatively be brightly coloured so as to appeal to children.

15 In accordance with a second aspect of the invention, there is provided a kit comprising a plurality of orthoses as described herein, the orthoses being of varying size and shape for fitting to feet of different sizes and shapes. The kit may also comprise differently coloured orthoses to allow the matching of the colour of the orthosis to the skin colour of the patient.

20 In accordance with a further aspect of the invention, there is provided an ankle-foot orthosis for resisting plantarflexion of a patient's foot, the orthosis comprising: a resilient rib locatable, in use, along and in abutment with at least a portion of the dorsal aspect of the patient's foot and at least a portion of the patient's lower leg, the orthosis comprising means for securing the rib to the patient's foot and lower leg.

25 In one embodiment, the securing means comprises a first strap means securable about one end of the rib and the patient's lower leg, and a second strap means securable about the other end of the rib and the patient's foot.

30 In another embodiment, the securing means comprises a first strap means securable about one end of the rib and the patient's lower leg and a shoe for securing the other end of the rib to the patient's foot.

In another embodiment, the securing means comprises an adhesive, at least end

portions of the rib being adhered to the patient's lower leg and foot.

In any event, it is preferred that the rib is of plastics, such as polypropylene or ortholene.

Preferably, the orthosis is skin coloured and/or fabricated by injection moulding. The orthosis could be formed by stamping from sheet material. The orthosis could be brightly coloured so as to appeal to children.

In accordance with another aspect of the invention, there is provided a kit comprising a plurality of orthoses as described herein, the orthoses being of varying size and shape for fitting to feet of different sizes and shapes. The kit may also 10 comprise differently coloured orthoses to allow the matching of the colour of the orthosis to the skin colour of the patient.

Embodiments of the present invention will now be described, by way of example only, with reference to the accompanying drawings, in which:

15 Figures 1a and 1b are schematic representations of one previously proposed orthosis;

Figures 2a and 2b are schematic representations of another previously proposed orthosis;

Figure 3 is a schematic representation of an orthosis according to a first aspect of the invention; and

20 Figure 4 is a schematic representation of an orthosis according to a second aspect of the invention.

Figure 5 is a schematic representation of an orthosis according to a third aspect of the invention;

Figure 6 is a side view of the orthosis of Figure 5; and

25 Figure 7 is a schematic representation of an orthosis according to a fourth aspect of the invention.

With reference to Figure 3, the orthosis 32 comprises a resiliently flexible sock-like structure 34 and a reinforcing means 36 (shown in ghost), which in this embodiment is a tape 38 - the ends of which are joined together to form a figure-of-30 eight which passes under the instep, behind the ankle and crosses on the dorsal aspect of the foot. The reinforcing means may be formed integrally with the sock-like

rubbers and other substances and thus it is preferred for the fabrication of the orthosis to be conducted in a thoroughly cleaned area.

Figure 5 is a schematic representation of another embodiment of orthosis 1 that comprises a resilient rib 3 that is locatable in use along the dorsal aspect of the 5 patient's foot 5. As shown, the orthosis 1 extends from approximately the base of the patient's toes up to the lower portion of the patient's shin.

The rib 3 is formed of a material that is preferably relatively light-weight and resilient - such as a plastic. A preferred material is ortholene or polypropylene, but numerous other suitable materials (such as a metal, an alloy or carbon fibre or similar 10 material for example) will be apparent to persons skilled in the art. The orthosis could be injection moulded, or for a more precise fit could be individually fitted to a patient's foot.

In order for the orthosis to benefit the patient, it must somehow be secured to the patient's foot. In the embodiment of Figure 5, the orthosis 1 is secured to the foot 15 5 by way of a pair of straps 7, which in the preferred embodiment include mechanical hook-and-loop fasteners (not shown) such as velcro^R that enable the straps 7 to be secured around the patient's foot and lower leg respectively. Alternative fastening mechanisms, such as pop fasteners, could be provided in addition or instead of velcro^R. When the straps are secured about the patient's foot and lower leg, the orthosis 1 is 20 secured to the patient's foot and plantarflexion is resisted. The arrangement of Figure 5 is particularly advantageous for use in warmer climates as the majority of the patient's foot is not covered by the orthosis 1.

Figure 6 is a side view of the orthosis 1 of Figure 5 illustrating the points at which pressure is applied to the patient's foot by the device. As shown, the orthosis 25 1 applies pressure to the patient's foot at three discrete locations (i), (ii) and (iii). Application of pressure to the foot at these three locations causes plantarflexion to be resisted whilst also aiding dorsiflexion. In this way, the orthosis 1 aids the patient during all stages of the walking motion. Furthermore, the orthosis 1 shown is considerably more comfortable for the patient to wear than previously proposed 30 devices as it does not extend beneath the foot and thus the weight of the patient does not bear upon the orthosis 1 during walking.

A further embodiment of the invention is shown in Figure 7. This embodiment of the invention is primarily designed for use in conjunction with a shoe 9, and comprises an orthosis 1 of polypropylene, for example, and a single strap 11 provided at the end of the reinforcing means closest to the patient's leg, in use. Securing the 5 strap 11 around the patient's lower leg and inserting the foot 5 and orthosis 1 within a shoe 9 provides an orthosis that is capable of resisting plantarflexion of the patient's foot. As an alternative to providing a strap, the upper end of the orthosis could be adhered to the patient's lower leg.

If the straps of the orthosis of Figure 5 are removably attached to the rib 3, 10 then the orthosis of Figure 5 could be converted for use with a shoe, as shown in Figure 7, simply by removing the lower strap.

As a further alternative that is not illustrated in the drawings, the straps could be dispensed with and the rib could then be adhered at least at the ends thereof to the Patient's lower leg and foot. The adhesive could be any adhesive suitable for bonding 15 articles to skin.

The orthosis of either embodiment may be coloured so that it can be matched to the skin colour of the patient, and may be provided in a variety of different shapes and sizes.

The orthosis may be of a variety of different materials chosen to have a 20 suitable resilience. For example, the orthosis could be of rubber, silicone, plastics, carbon fibre or of any other material apparent to persons skilled in the art. In a preferred example, the orthosis is of 35 shore silicone elastomer. The orthosis may be of a greater or lesser shore value depending upon the particular needs of the patient to which it is to be fitted.

25 It will be understood, of course, that the invention has been described herein by way of example only and that modifications may be made within the scope of the invention.

CLAIMS

1. An ankle-foot orthosis for resisting plantarflexion of a patient's foot, the orthosis comprising: a resiliently flexible sock-like structure enveloping, in use, at least a portion of a patient's lower leg in the vicinity of the ankle and at least a portion of the plantar and dorsal aspects of the patient's foot.
5
2. An orthosis according to Claim 1, comprising a reinforcing means for further resisting planterflexion of the foot.
- 10 3. An orthosis according to Claim 2, wherein the reinforcing means comprises a length of tape, the ends of the tape being joined together to form a figure-of-eight passing under the instep, behind the ankle and crossing on the dorsal aspect of the foot.
- 15 4. An orthosis according to Claim 2, wherein the reinforcing means comprises a rib running along at least a portion of the dorsal aspect of the foot and substantially midway between the medial malleolus and the lateral malleolus.
- 20 5. An orthosis according to Claim 4, wherein the sock-like structure is defined by the rib and a pair of straps, one secured to either end of the rib and respectively securable about the plantar aspect of the foot and the portion of the patient's lower leg in the vicinity of the ankle.
- 25 6. An orthosis according to any of Claims 2 to 5, wherein the reinforcing means has a greater resilience than the sock-like structure.
- 30 7. An orthosis according to any of Claims 1 to 6, comprising an insertion slit extending substantially midway between the medial malleolus and the lateral malleolus at the back of the ankle towards the calcaneum, means being provided to securely close the slit once the patient's foot has been inserted in the orthosis.

8. An orthosis according to Claim 7, wherein the closing means comprises a mechanical hook and loop fastener, a set of hoops or hooks being provided adjacent one edge of the slit and a corresponding set of hooks or hoops being provided on a closure member affixed to the other side of the slit, respective hooks and loops being 5 connectable to securely close the slit.
9. An orthosis according to Claim 7, wherein the closure member comprises a zip fastener secured to opposite sides of the slit.
10. An orthosis according to Claim 9, wherein the closure member comprises a set of eyelets provided on either side of the slit, the slit being closable by a lace fed through the eyelets.
11. An orthosis according to any preceding claim, wherein the orthosis envelops 15 at least a portion of the dorsal and plantar aspects of the foot without enveloping the toes.
12. An orthosis according to any preceding claim, wherein the orthosis envelops at least a portion of the plantar aspect of the foot without enveloping the calcaneum.
13. An orthosis according to any preceding claim, wherein the sock-like structure is of silicone.
14. An orthosis according to Claim 13, wherein the sock-like structure is a 35 shore silicone elastomer.
15. An orthosis according to Claim 2 and to any of Claims 3 to 14 when dependent upon claim 2, wherein the reinforcing means is of silicone.
- 30 16. An orthosis according to Claim 2 and to any of Claims 3 to 14 when dependent upon claim 2, wherein the reinforcing means is of a different material to that of the

sock-like structure.

17. An ankle-foot orthosis for resisting plantarflexion of a patient's foot, the orthosis comprising: a resilient rib locatable, in use, along and in abutment with at least a portion of the dorsal aspect of the patient's foot and at least a portion of the patient's lower leg, the orthosis comprising means for securing the rib to the patient's foot and lower leg.

18. An orthosis according to Claim 17, wherein the securing means comprises a first strap means securable about one end of the rib and the patient's lower leg, and a second strap means securable about the other end of the rib and the patient's foot.

19. An orthosis according to Claim 17, wherein the securing means comprises a first strap means securable about one end of the rib and the patient's lower leg and a shoe for securing the other end of the rib to the patient's foot.

20. An orthosis according to Claim 17, wherein the securing means comprises an adhesive, at least end portions of the rib being adhered to the patient's lower leg and foot.

21. An orthosis according to any of Claims 17 to 20, wherein the rib is of plastics.

22. An orthosis according to any of Claims 17 to 20, wherein the rib is of silicone.

25 23. An orthosis according to any of Claims 17 to 21, wherein the rib is of polypropylene.

24. An orthosis according to any of Claims 17 to 20, wherein the rib is of ortholene.

30 25. An orthosis according to any of Claims 17 to 20, wherein the rib is of carbon

fibre.

26. An orthosis according to any preceding claim, wherein the orthosis is skin coloured.

5

27. An orthosis according to any preceding claim, wherein the orthosis is fabricated by injection moulding.

10 28. An orthosis according to any of Claims 17 to 20, wherein the orthosis is stamped or pressed from sheet material.

29. A kit comprising a plurality of orthoses according to any preceding claim, the orthoses being of varying size and shape for fitting to feet of different sizes and shapes.

15

30. A kit according to Claim 29, comprising differently coloured orthoses to allow the matching of the colour of the orthosis to the skin colour of the patient.

20 31. An orthosis substantially as hereinbefore described with reference to Figures 3 or 4, or to Figures 5, 6 and 7 of the accompanying figures.

32. A kit substantially as hereinbefore described.